Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0506298	01/20/2021
Name of Provider or Supplier	**Street Address, City, State**	
Dimmit Regional Hospital	704 Hospital Drive, Carrizo Springs, TX	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor observation and confirmed in interview of facility personnel, the laboratory failed to identify 3 of 3 reagents found in Coplin jars with lot number and expiration date. The findings were: 1. Surveyor observation on January 18, 2021 at 13: 52 hours in the laboratory found three (3) Coplin jars that contained reagents. The jars were not labeled with lot number or expiration date. Jar 1: Fixative Solution I No Lot Number No Expiration Date Jar 2: Fixative Solution II No Lot Number No Expiration Date Jar 3: Deionized Water No Lot Number No Expiration Date: 2. Reagent Log posted in the Hematology Department documented when reagents were changed but also did not include lot numbers or expiration dates. 3. Interview with the Laboratory Manager on January 18, 2021 at 14:00 hours in the laboratory confirmed the findings.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when

they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's IQCP (Individualized Quality Control Plan) for D-Dimer, Mono, Rheumatoid Factor, Helicobacter pylori, and Leuko EZ Vue, review of the laboratory's quality control records, review of patient test logs, and confirmed in interview of facility personnel it was revealed that the laboratory failed to have documentation of a complete risk assessment that identified the sources of error and evaluate the frequency and impact of those sources on the quality of testing. The findings were: Note: Manufacturer-provided tools and templates, if available, may be helpful for laboratories implementing IQCP; however, laboratories need to supplement these materials with laboratory-specific information as part of the Risk Assessment. The manufacturer information is not sufficient in and of itself. In-house data, established by the laboratory in its own environment and by its own personnel, must be utilized to demonstrate that the stability of the test system as it is used in the laboratory supports the number and frequency of the QC documented in the Quality Control Plan (QCP). 1. A review of the laboratory's IQCP studies for D-Dimer, Mono, Rheumatoid Factor, Helicobacter pylori, Leuko EZ Vue, and Sensititre for antibiotic susceptibility found the plans were incomplete. The risk assessment failed to include the evaluation of frequency and impact of possible sources of error obtained from the laboratory's own data. 2. Review of the IQCP studies found the laboratory utilized only the manufacturer's instructions to develop the plans. The laboratory did not utilize either previous EQC (Equivalent Quality Control) plans or new studies to develop its plan to perform testing with each new lot number, new shipment, and every 30 days. 3. A review of the laboratory's quality control records from March 1, 2020 to April 30, 2020 found that the laboratory performed quality control testing procedures as follows: Mono Spot Two levels of external quality control performed on: March 1, 2020 (Kit Lot #B31960) April 1, 2020 (Kit Lot #B31960) RA Factor Two levels of external quality control performed on: March 1, 2020 (Kit Lot #B30982) March 23, 2020 (Kit Lot #B32356) new lot number April 1, 2020 (Kit Lot #B2356) April 3, 2020 (Kit Lot #B32356) Helicobacter pylori Two levels of external quality control performed on: March 1, 2020 (Kit Lot #HP8720025) April 1, 2020 (Kit Lot #HP9082011) Leuko EZ Vue Two levels of external quality control performed on: 03-01-2020 (Kit Lot #0619044) 04-01-2020 (Kit Lot #0619044 Sensititre March 2, 2020 March 9, 2020 March 16, 2020 March 23, 2020 March 30, 2020 April 6, 2020 April 13, 2020 April 20, 2020 April 27, 2020 4. Review of the laboratory's patient test logs from March 1, 2020 to April 31, 2020 found the following patients were tested when the laboratory's IQCP studies were incomplete: Mono Spot No patients tested in March or April 2020 RA Factor Accession No.: 25162 Result Date: March 6, 2020 Result: Negative Accession No.: 25399 Result Date: March 7, 2020 Result: Negative Accession No.: 28913 Result Date: March 25, 2020 Result: Negative Accession No.: 29774 Result Date: March 30, 2020 Result: Positive Accession No.: 30105 Result Date: April3, 2020 Result: Negative Helicobacter pylori Accession No.: 24363 Result Date: March 8, 2020 Result: Positive Accession No.: 27468 Result Date: March 12, 2020 Result: Positive Accession No.: 27530 Result Date: March 17, 2020 Result: Negative Accession No.: 28867 Result Date: March 24, 2020 Result: Negative Accession No.: 28801 Result Date: March 24, 2020 Result: Positive Accession No.: 28903 Result Date: March 24, 2020 Result: Negative Accession No.: 29906 Result Date: March 31, 2020 Result: Negative Accession No.: 29926 Result Date: March 31, 2020 Result: Negative Accession No.: 29874 Result Date: March 31, 2020 Result: Negative Accession No.:

	29988 Result Date: March 31, 2020 Result: Negative Accession No.: 30014 Result Date: March 31, 2020 Result: Negative Accession No.: 31377 Result Date: April 7, 2020 Result: Positive Accession No.: 31385 Result Date: April 7, 2020 Result: Negative Accession No.: 31430 Result Date: April 7, 2020 Result: Negative Accession No.: 32780 Result Date: April 15, 2020 Result: Negative Accession No.: 34019 Result Date: April 21, 2020 Result: Negative Accession No.: 35347 Result Date: April 27, 2020 Result: Negative Accession No.: 35510 Result Date: April 28, 2020 Result: Leuko EZ Vue Accession No.: 31689 Result Date: April 9, 2020 Result: Positive Accession No.: 34350 Result Date: April 22, 2020 Result: Positive Sensititre (See Patient Alias List) 5. An interview with the Laboratory Manager on January 19, 2021 at 12:45 hours confirmed the findings. He revealed that he used only the manufacturer's instructions to develop the IQCP studies.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory's verification studies performed on the epoc blood gas analyzer (serial number 04884) in May 2019, review of patient test records from 2020, and staff interview, it was revealed the laboratory failed to have documentation of performing corrective actions when patient results exceeded the laboratory's established reportable range. The findings were: 1. A review of the laboratory's verification studies performed on the epoc blood gas analyzer (serial number 04884) in May 2019 revealed the laboratory verified reportable range for PCO2 was determined to be 3.5 - 110.5. 2. A review of patient test records from 2020 revealed the laboratory reported a PCO2 value above the verified reportable range. It was: a) Test date: 10/01/2020 Patient ID: 10194681 PCO2 value: 162.8 3. The laboratory was asked to provide documentation of performing corrective actions for the identified result. No documentation was provided. 4. An interview with the laboratory administrative director on 01/20/2021 at 1045 hours in the respiratory department - after his review of the records- confirmed the findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by:

	Based on review of the laboratory's College of American Pathologist (CAP) linearity records and confirmed in interview of facility personnel revealed the laboratory failed to have a quality assessment policy that identified and corrected when the laboratory failed to ensure remedial actions were taken on calibration verification results for analytes that were documented as imprecise for 2 of 10 analytes reviewed by the proficiency testing agency. The findings were: 1. Review of the laboratory's CAP linearity records for Event LN2-2020 found the following 2 of 10 analytes reviewed were identified by the proficiency agency as, "Imprecise (Poor Repeatability and/or Fit)." "Phosphorus Interpretation: Your diluted results show inconsistent recovery and /or large differences between replicate assays. Suggested Actions: -Review your dilution protocol, including appropriateness of the diluents. -Ensure that your dilution protocol is followed. -Rely on calibration verification results for undiluted specimens. -If your calibration verification evaluation is Different, recalibrate and consider rerunning a linearity study. Document investigation and corrective action here or on the CVL Investigation Checklist." and; HDL Cholesterol Interpretation: your results show both poor agreement with the best-fit line or curve and large differences between assay replicates. Suggesting Actions: -Review specimen handling procedures. Incomplete thawing, inadequate mixing, or improper temperatures can cause problems. -Check for evidence of test system malfunction. Pipetting errors, temperature fluctuations, or optical system problems can contribute to large analytical errors. -If unable to resolve, consider recalibration. Document investigation and corrective action here or on the CVL Investigation Checklist." 2. The laboratory was asked to provide documentation of ensuring remedial action was performed. No documentation was provided. 3. An interview with the Laboratory Manager on January 19, 2021 at 16:20 hours in his office confirmed the findings. Key: CVL - Calibration Verification Linearity HDL - high density lipoprotein
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of patient test reports from September 2020 to October 2020, and staff interview, it was revealed the laboratory failed to provide normal ranges for 3 of 4 samples types for blood gas analysis. The findings were: 1. A review of patient test reports from September 2020 to October 2020 revealed the laboratory had the following defined patient normal ranges for arterial blood gas results: pH 7.34-7.46 PCO2 35.0-45.0 PO2 77.0-97.0 HCO3 20.0-28.0 Base excess -0.3-3.0 O2 Saturation 95 - 98 2. Further review of the patient test reports revealed the laboratory performed blood gas analysis on 4 additional types of patient samples: venous blood gas arterial cord blood venous cord blood capillary (heel stick) All samples types were performed under the order for an arterial blood gas. 3. The laboratory was asked to provide documentation of providing normal ranges for each of these additional sample types. No documentation was provided. 4. An interview with the laboratory administrative director on 01/20/2021 at 1100 hours in the respiratory office revealed all samples were reported with the normal ranges for arterial blood gas. He agreed that each sample type required its own normal ranges. This confirmed the findings.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of quality control records, patient final reports, and confirmed in interview of facility personnel, the laboratory director failed to ensure the laboratory's quality control plan identified QC errors as they occurred (refer to D5441)
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on review of patient test reports from September 2020 to October 2020, and staff interview, it was revealed the laboratory director failed to ensure test reports include pertinent information needed for interpretation for 3 of 4 samples types for blood gas analysis (refer to D5807).
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted plan of correction, review of quality control records, review of patient records, and confirmed in interview of facility personnel, the technical consultant failed to establish an appropriate quality control program with defined acceptable levels of analytic performance and maintained throughout the testing process (refer to D5441 and D5445).
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and

	assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted plan of correction, review of manufacturer's instructions, review of quality control records, review of environmental records, and confirmed in interview of facility personnel, the technical consultant failed to identify testing personnel training needs (refer to D5417, D5441, D5545, D5469, D5801, and D5807).